



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-16AVB]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

### **Proposed Project**

US Zika Pregnancy Registry - New - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

### **Background and Brief Description**

In May 2015, the World Health Organization reported the first local transmission of Zika virus in the Western

Hemisphere, with autochthonous cases identified in Brazil. As of March 16, 2016, local transmission has been identified in at least 32 countries or territories in the Americas. Further spread to other countries in the region is likely. Local vectorborne transmission of Zika virus has not been documented in the 50 U.S. states or the District of Columbia, but has occurred in US territories, including in Puerto Rico, the US Virgin Islands, and American Samoa. However, Zika virus infections have been reported in travelers returning to the United States from areas with active Zika virus transmission. Zika virus infection also has occurred through sexual transmission, which may pose an additional risk to non-travelling pregnant women whose partners may have traveled to areas at high risk for Zika virus acquisition. With the ongoing outbreak in the Americas, the number of Zika virus disease cases among travelers returning to the United States likely will increase, and sexual transmission from male travelers to their sex partners in the United States will likely continue to occur. In addition, mosquito-borne local transmission may occur in states where Aedes species mosquitoes are present.

In some Brazilian states where Zika virus transmission has occurred, there has been an increase in cases of infants born with microcephaly. Zika virus infections have been confirmed in

several infants with microcephaly and in fetal losses in women infected during pregnancy. In addition to microcephaly, a range of other problems have been detected among fetuses and infants infected with Zika virus before birth, such as absent or poorly developed brain structures, defects of the eye, hearing deficits, and impaired growth. The Ministry of Health in Brazil, with support from the Pan American Health Organization (PAHO), the U.S. Centers for Disease Control and Prevention (CDC), and other partners, is investigating the association between Zika virus infection and microcephaly, as well as other adverse pregnancy and infant outcomes.

As part of the public health response to the Zika virus disease outbreak, CDC will conduct supplemental surveillance of antenatal diagnostic testing and clinical outcomes among pregnant women with laboratory evidence of Zika virus or unspecified flavivirus infection and their infants through the U.S. Zika Pregnancy Registry. It is anticipated that the Registry will provide critical information to direct CDC clinical recommendations and public health guidance and messages.

The objective of this Registry is to monitor the frequency and types of pregnancy and infant outcomes following Zika virus

infection during pregnancy, so as to inform ongoing response efforts for this Zika virus disease outbreak, including recommendations for clinical care, planning for services for pregnant women and infants affected by Zika virus, and improved prevention of Zika virus infections during pregnancy.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 2,167.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
State, Territorial and Local Health Departments	Maternal Health History Form	100	10	30/60
	Supplemental Imaging Form	100	10	10/60
	Laboratory Results Form	100	10	15/60
Clinicians and Other Providers	Assessment at Delivery Form	100	10	30/60
	Infant Health Follow-Up Form	100	30	15/60

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Office of the Director  
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[FR Doc. 2016-16872 Filed: 7/15/2016 8:45 am; Publication Date: 7/18/2016]